

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 14-R-0014
CUSTOMER NUMBER: 108

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

General Hospital Corporation
Massachusetts General Hospital
32 Fruit Street
Boston, MA 02114

Telephone: (617)-724-5151

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs			23		23
7. Hamsters			2	4	6
8. Rabbits		12	244	6	262
9. Non-human Primates			98		98
10. Sheep		2	107		109
11. Pigs	415		567		982
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

66, b7c

66, b7c

DATE SIGNED

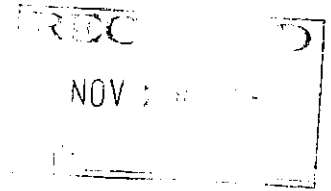
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APHIS Form 7023 Site List

**Annual Report of Research Facility
Reporting Facility Locations**

For the period October 1, 2005-September 30, 2006



Registration Number: 14-R-0014

Customer Number: 108

General Hospital Corporation

32 Fruit Street

Boston, MA 02114

Reporting Facilities:

b2high, b7f

b2high, b7f

**APHIS Form 7023
Annual Report of Research Facility**

Column E Explanation - Rabbits

For the period October 1, 2005-September 30, 2006

(added to the original Annual Report on July 18, 2007)

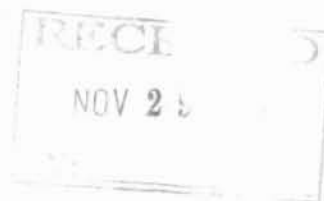
1. Registration Number: 14-R-0014
2. Number of animals used in the study in the reporting period: 3
3. Species (common name) of animals used in the study: *Oryctolagus cuniculus*
4. Explanation of the procedure producing pain or distress: three rabbits on an approved protocol for evaluating drug-coated stents to reduce or prevent arterial stenosis were found dead in their cages three days after stent implantation, presumably resulting from unintended strokes.
5. Scientific justification as to why pain or distress could not be relieved, plus methods or means used to determine that pain or distress would interfere with test results: N/A since the animals were found dead, with no prior clinical signs observed that would have indicated additional veterinary support.
6. Federal regulations that require this procedure: N/A.

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Column E Explanation - Hamsters

For the period October 1, 2005-September 30, 2006



1. Registration Number: 14-R-0014
2. Number of animals used in the study in the reporting period: 4
3. Species (common name) of animals used in the study: *Mesocricetus auratus* (Syrian hamster)
4. Explanation of the procedure producing pain or distress: this protocol produces monoclonal hybridomas from immunized hamsters that are subsequently purified and used to study the inflammatory response in another rodent model. A portion of this study requires challenging hamsters with lipopolysaccharide (LPS) to produce an inflammatory response.
5. Scientific justification as to why pain or distress could not be relieved, plus methods or means used to determine that pain or distress would interfere with test results: analgesics or anti-inflammatory agents cannot be used as these agents will alter the distribution of LPS and may bias the experiment. Every effort is made to minimize any potential pain or distress that may be experienced including the use of low doses of LPS administration, increased monitoring frequency, and short duration of study (less than 2 hours).
6. Federal regulations (if any) that require this procedure: N/A

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Column E Explanation - Rabbits

For the period October 1, 2005-September 30, 2006

1. Registration Number: 14-R-0014
2. Number of animals used in the study in the reporting period: 3
3. Species (common name) of animals used in the study: *Oryctolagus cuniculus*
4. Explanation of the procedure producing pain or distress: this protocol performs non-clinical safety testing of diagnostic radiopharmaceuticals for FDA-approved drugs linked to radioactive tracers or new chemical entities intended for physician-sponsored IND applications. Animals are administered candidate imaging agents and evaluated for up to 14 days for evidence of any side effects.
5. Scientific justification as to why pain or distress could not be relieved, plus methods or means used to determine that pain or distress would interfere with test results: the goal is to evaluate these compounds for signs of toxicity so analgesics or anti-inflammatory agents cannot be used because they may mask a toxic response. Every animal is closely monitored and the study is terminated early in the event of a severe adverse reaction by euthanizing the affected animal.
6. Federal regulations that require this procedure: US Food and Drug Administration –
 - a. "Industry Guidelines. Developing Medical Imaging Drug and Biological Products. Part 1: Conducting Safety Assessments (available at <http://www.fda.gov/cber/gdlns/medimagesaf.htm>);
 - b. "Guidance for Industry. Single Dose Acute Toxicity Testing for Pharmaceuticals" (available at <http://www.fda.gov/cder/guidance/pt1.pdf>).

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Animal Welfare Act Exceptions Approved by the IACUC

For the period October 1, 2005-September 30, 2006



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Exception: The Subcommittee on Research Animal Care (SRAC) approved an exception regarding housing space for individual pigs. Pigs transplanted with organs or pigs that serve as fetal tissue donors and that weigh between 100-130 Kg are occasionally maintained in a barrier facility. Those pigs are kept in the largest pens available that provide only 25 square feet of floor space. This cage floor area is considered adequate for conventional pigs up to but not exceeding 100 Kg, according to the "Guide for the Care and Use of Laboratory Animals" (the *Guide*; National Research Council, 1996). Staff veterinarians from the Center for Comparative Medicine review this situation with the Principal Investigator and examine the pigs in question on an as needed basis. No adverse effects have been observed regarding the health of these animals. The SRAC finds that pigs over 100 Kg body weight to be sufficiently comfortable in these pens and are able to assume all normal body positions without complications.

Exception: The SRAC approved an exception to the *Guide* for providing feed on the cage floor for rodents, including those covered by the Animal Welfare Act, under specific circumstances. The justifications for this exception are to provide access to feed for animals that may have had surgery or neurodegenerative conditions that limit their movement, and for hamsters that may be debilitated during the course of a protocol to not easily reach feed normally provided in overhead hoppers.

Exception: The SRAC approved an exception for baboons maintained in intensive care following an organ transplant. During their recovery, some animals may not be acceptable candidates for chemical sedation that is required to move them to clean cages. Thus, these animals may remain undisturbed and not transferred from their recovery cage for up to 21 consecutive days post-surgery, versus the maximum 14 days provided in the *Guide* and Animal Welfare Act. Spot cleaning of cage bars and switching to clean cage pans will be performed as needed, in the meantime.